Inspection report on compliance with HTA licensing standards
Site visit date(s): **19 October 2021**
Virtual Regulatory Assessment (VRA) date(s): **20-21 October 2021**

London Bridge Hospital

HTA licensing number 11069

Licensed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)

Licensable activities carried out by the establishment

Licensed activities

'E' = Establishment is licensed to carry out this activity and is currently carrying it out.

'E*' = Establishment is licensed to carry out this activity but is not currently carrying it out.

'SLA' = Service Level Agreement; the establishment is licensed for this activity, but another licensed establishment carries out the activity on their behalf.

Site	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Hub **London Bridge Hospital**	E*/SLA			E			
Satellite **The Princess Grace Hospital**	E*			E			

Satellite **The Wellington Hospital**	E*			E*			
Satellite **The Harley Street Clinic**	E						
Satellite **Hospital Corporation of America (HCA) Laboratories - Shropshire House**			E*				

Tissue types authorised for licensed activities

Authorised = Establishment is authorised to carry out this activity and is currently carrying it out.
Authorised* = Establishment is authorised to carry out this activity but is not currently carrying it out.

Tissue Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Progenitor Cell, Haematopoietic, PBSC; PBSC	Authorised*		Authorised*				
Musculoskeletal, Bone; Bone				Authorised			

Musculoskeletal, Tendon & Ligament; Tendons				Authorised			
Musculoskeletal, Tendon & Ligament; Ligaments				Authorised			
Skin; Skin				Authorised*			
Membrane, Fascia Lata; Fascia Lata				Authorised*			
Neuronal; Nerves				Authorised*			
Cardiovascular, Valves; Heart Valves				Authorised*			
Musculoskeletal, Cartilage; Cartilage				Authorised			
Musculoskeletal, Tendon & Ligament; Menisci				Authorised			
Musculoskeletal, Cartilage; Cartilage (ATMP)	Authorised*		Authorised*				
Other; Tumour (ATMP)	Authorised		Authorised*				

Summary of inspection findings

The HTA found the Designated Individual (DI) and the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

Although the HTA found that London Bridge Hospital (the establishment) had met the majority of the HTA's standards, nine minor shortfalls were found against standards for Governance and Quality, and Premises, Facilities and Equipment.

The HTA has assessed the establishment as suitable to be licensed for the activities specified, subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Compliance with HTA standards

Minor Shortfalls

GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.	The establishment does not have documented procedures in place for the procurement of tumour tissue. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**
d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.	A minor shortfall was raised at the previous inspection with regards to an inconsistent approach to document control at the establishment. As part of the corrective and preventative action (CAPA) plan, the establishment agreed to implement a two-year review period for documents relating to HTA licensable activities. However, at the time of this inspection, two of the establishment's policies were not aligned with this requirement.	**Minor**

GQ2 There is a documented system of quality management and audit.		
b) There is an internal audit system for all licensable activities.	The establishment's independent and internal audits are currently captured on spreadsheets. During a review of the audits, it was unclear whether comments captured against the standards were recorded by the auditor or the auditee. It was noted that the auditor's name was recorded incorrectly on two of the independent audits. In some audits, there was no record of what evidence was looked at to verify compliance with the standards and one of the findings raised by the auditor in an independent audit was not addressed by the establishment as part of the CAPA plan. The establishment's current audit system does not provide assurance that audits are robustly completed and accurately recorded, and that any findings and corrective actions will be fully addressed.	**Minor**
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.		

GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.		
b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 001/2021.	Princess Grace Hospital (PGH) is licensed to procure cartilage tissue which is sent to Germany to be manufactured into an Advanced Therapy Medicinal Product (ATMP). The testing of a donor from whom tissue was procured was not carried out in accordance with the establishment's procedures or the regulatory requirements stipulated by Directions 001/2021. *The DI confirmed that the establishment stopped procurement of cartilage after this procurement event and they no longer carry out this activity. If the establishment wishes to resume this activity in the future, the DI must contact the HTA first for authorisation. This shortfall has been closed.*	**Minor**

GQ7 There are systems to ensure that all adverse events are investigated promptly.		
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.	The establishment uses an electronic system to report and record adverse incidents. Some of the incident records reviewed during the inspection did not contain sufficient detail to fully capture what had happened, the factors that were considered during the investigation into the root cause of the event, the potential impact on the quality and safety of the tissues and cells, and the CAPAs implemented to mitigate the risk of recurrence.	**Minor**

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.		
c) Staff can access risk assessments and are made aware of local hazards at training.	There are a number of staff involved with licensable activities who do not have access to the establishment's risk assessments. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.		
d) There is a documented, specified maximum storage period for tissues and / or cells.	The establishment does not have procedures in place to ensure that suppliers are provided with up-to-date information about the storage conditions available at each site. During a review of disposal records, it was noted that one femoral head was assigned a reduced six-month expiry date because the supplier was not provided with updated information about the temperature at which the bone would be stored after receipt. This led to the disposal of a femoral head which might have been used in patient treatment if the correct expiry date was applied. In the above example, there was a discrepancy with the establishment's assigned expiry date which exceeded the supplier's expiry date by one day. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.		
d) New and repaired equipment is validated before use and this is documented.	The establishment does not have a procedure in place to ensure that equipment that is serviced and/or repaired is fit for purpose and operating at the correct settings before it is returned to use. Following a service of the temperature monitoring system at the hub, the system was not returned to the correct settings by the engineer. This led to the loss of temperature data for tissues and cells stored in the freezer. Furthermore, as the automated notifications were deactivated, alerts were not sent out to the establishment during this time.	**Minor**
f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded.	The establishment's freezer at PGH was not maintained in accordance with the frequency stipulated in the establishment's policy (HCAUK.SS.HTA.POL.1005), which stipulates that each freezer should be defrosted and cleaned every six-months as a minimum. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

Advice

The HTA advises the DI to consider the following to further improve practice:

Number	Standard	Advice
1.	GQ1d	The DI is advised to ensure that all documents relevant to the establishment's activities are adequately controlled and managed within the establishment's document control system. Examples include flowcharts displayed on the freezers that act as a visual aid for staff in the event of a temperature excursion, and the forms that are used to record daily freezer temperatures and the weight of the carbon dioxide cylinders. The DI is also advised to ensure that a version of the original audit record is retained by the establishment so that it is possible to refer back to the auditor's original audit document, if the need arises.
2.	GQ2b, GQ2c	The DI is advised to review the licensing standards used in audits templates to ensure that audits are performed against the up-to-date standards and HTA Directions 001/2021, which have superceded Directions 003/2010 and 002/2018.
3.	GQ3e	During a review of establishment records, it was noted that there was an inconsistent approach to completing the tissue cold chain information on the tissue tracking forms. The DI is advised to provide refresher training on the completion of the tissue tracking forms in line with the establishment's procedures.
4.	GQ3k	During the inspection, concerns were raised to the HTA regarding current staffing levels at PGH, which are stretched due to an increase in clinical commitments. The establishment is advised to review whether the current staffing levels are sufficient to manage the licensable activities at PGH in order to maintain regulatory compliance or whether additional staffing resource is required.
5.	GQ4b, GQ3e, GQ2c	During a review of tissue tracking forms, examples of overwriting were seen which sometimes made the information illegible; this was also raised as a finding during one of the establishment's independent audits. The

		DI is advised to re-train staff to ensure records are legible and accurate, and is further advised to ensure that audit findings are followed up and resolved in a timely manner.
6.	GQ6b	The DI is advised to record the time of tissue receipt at the establishment so that a full audit trail is maintained and to enable the establishment to check that tissues and cells are not stored beyond 48 hours except under an appropriate storage licence.
7.	PFE5a	The establishment is advised to challenge the freezer alarms on a regular basis to ensure the systems are fully functioning, alerts are sent to the relevant members of staff, and that staff can respond appropriately. The DI is also advised to check the temperature monitoring intervals are consistent and in line with the establishment's procedures.
8.	PFE5c	The establishment uses a carbon dioxide cylinder system to back up the freezers in the event of a power failure. The DI is advised to update the relevant procedure(s) to specify the weight limit at which the carbon dioxide cylinder would need to be replaced.
9.	D2a, GQ2b, GQ3e	During a review of disposal records at the hub, it was noted on one occasion that the reason for tissue disposal was not recorded. The DI is advised to incorporate a regular audit of disposal records into the internal audit systems, to ensure reasons for the disposal of tissue are captured. The DI is further advised to provide refresher training on the completion of the tissue tracking forms in line with the establishment's procedures.

Background

London Bridge Hospital (LBH) has been licensed by the HTA since December 2006. This was the eighth inspection of the establishment; the most recent previous inspection took place in March 2020.

Since the previous inspection, the establishment has added the storage of new tissue types (heart valves, cartilage, meniscus) following an annual activity submission in 2021. The licensable activity of testing, previously undertaken at the HCA Laboratories satellite, is currently inactive. The establishment has been instructed to notify the HTA before resuming any testing activities, as the HTA must be satisfied that appropriate systems and agreements are in place before this activity resumes.

LBH is the establishment's hub site and stores bone, tendons, ligaments, cartilage and menisci in a -80ºC freezer. LBH is authorised for storage of heart valves and skin tissue but is not currently carrying out this activity.

PGH stores bone, tendons and ligaments in a -80ºC freezer. This satellite has also procured cartilage tissue from one donor to date (*See Shortfall GQ5b*). The cartilage tissue is sent to Germany as a starting material for the manufacture of an ATMP. Following this procurement event, the testing activity at HCA Laboratories was voluntarily suspended by the establishment and the procurement of cartilage tissue is no longer being carried out. The HTA is not satisfied that appropriate systems and governance arrangements are in place to meet the regulatory requirements for this activity which includes up-to-date procedures, agreements, risk assessments, staff training and testing activities. The establishment must also ensure that an appropriate export licence is in place before sending the tissue outside of the United Kingdom for future ATMP manufacture.

The Wellington Hospital (TWH) is authorised to store tendons, ligaments, fascia lata and nerves. However, TWH no longer stores cellular tissues beyond 48 hours. If the tissues are not used, they may be returned to the supplier, provided that the box remains unopened and the manufacturer's stipulated timeframe has not been exceeded.

Harley Street Clinic (HSC) is licensed for the procurement of tumour tissue. Tissue is procured as the starting material for an ATMP manufactured at a site in London. Donor blood samples related to this activity are tested for mandatory serological markers under the authority of the manufacturer's

HTA licence. The pre-admission work up and blood sample collection are carried out at another hospital. Similarly, the leukapheresis collection following the tumour procurement is also carried out at another hospital.

LBH, PGH and TWH store a number of acellular tissue products at ambient temperature conditions such as acellular bone, demineralised bone matrix (DBM), DBM putty and cancellous bone particles.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The inspection team covered the following areas during the inspection:

Site visit inspection

The visual inspection took place at the hub, LBH and one of the four satellites, PGH. The inspection team inspected the freezers and cabinets where tissues are stored at both sites. The site visit inspection included a review of equipment maintenance records, staff training records, temperature monitoring data of the freezers and storage areas and discussions with the PDs and the DI about the reported incidents relating to their sites.

Traceability audits were carried out at LBH and PGH where the tissue products were cross-checked against the tissue register. The audits included:

- two tendons stored in the -80ºC freezer at the hub;
- four tissues used in human application at the hub;
- six tissues disposed of at the hub (*See Advice No. 9*);
- one tendon and one femoral head stored in the -80ºC freezer at PGH;
- one tissue used in human application at PGH; and
- one tissue disposed of at PGH (*See Shortfall PFE3d*).

VRA activities undertaken

The inspection team held a discussion with the Surgical Services Manager, two of the PDs from PGH and the DI regarding the work involving the procurement of cartilage tissue as a starting material for the manufacture of an ATMP. The incidents that arose from the procurement event in 2020 were also reviewed. It was apparent that there was a gap of over a year from when the staff were originally trained to when the first procurement was

carried out which may have led to the staff not being familiar with the procedure (*See Shortfall GQ5b*).

A VRA of the activities carried out at HSC included a traceability audit of records relating to tumour procurement from two donors. The paperwork associated with consent, procurement, courier arrangement, release of the sample and staff training records were reviewed with the PD as part of the audit. No discrepancies were noted. In addition to this, three reported incidents relating to HSC were discussed with the PD and the DI.

Policies and procedures relating to the licensable activities were reviewed prior to the VRA by the inspection team. A VRA was carried out for areas covering governance and quality systems which included a discussion with the DI regarding the establishment's audits, risk assessments, some of the reported incidents, record management, staff training, agreements with third parties and governance meetings.

Report sent to DI for factual accuracy: 16 November 2021

Report returned from DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 01 December 2021

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 16 May 2022

Appendix 1: The HTA's regulatory requirements

The HTA must assure itself that the DI, Licence Holder, premises and practices are suitable.

The statutory duties of the DI are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Appendix 2: Classification of the level of shortfall (HA)

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as ‘Critical’, ‘Major’ or ‘Minor’. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the Human Tissue Act 2004, Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended), or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant direct risk of causing harm to a recipient patient or to a living donor,

   or

   A number of ‘major’ shortfalls, none of which is critical on its own, but viewed cumulatively represent a systemic failure and therefore are considered ‘critical’.

   A critical shortfall may result in one or more of the following:

   - A notice of proposal being issued to revoke the licence
   - Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.
   - A notice of suspension of licensable activities
   - Additional conditions being proposed
   - Directions being issued requiring specific action to be taken straightaway

2. Major shortfall:

A non-critical shortfall.

A shortfall in the carrying out of licensable activities which poses an indirect risk to the safety of a donor or a recipient

or

A shortfall in the establishment's quality and safety procedures which poses an indirect risk to the safety of a donor or a recipient;

or

A shortfall which indicates a major deviation from the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) or the HTA Directions;

or

A shortfall which indicates a failure to carry out satisfactory procedures for the release of tissues and cells or a failure on the part of the designated individual to fulfil his or her legal duties;

or

A combination of several 'minor' shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall by adversely affecting the quality and safety of the tissues and cells.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. Minor shortfall:

A shortfall which cannot be classified as either critical or major and, which can be addressed by further development by the establishment.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based review or at the time of the next inspection.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with the final inspection report. Establishments must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.

Appendix 3: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

Human Tissue (Quality and Safety for Human Application) Regulations 2007 Standards (as amended)

Consent

Standard
C1 Consent is obtained in accordance with the requirements of the HT Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and as set out in the HTA's Codes of Practice.
a) If the establishment acts as a procurer of tissues and / or cells, there is an established process for acquiring donor consent which meets the requirements of the HT Act 2004 the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) and the HTA's Codes of Practice
b) If there is a third party procuring tissues and / or cells on behalf of the establishment the third party agreement ensures that consent is obtained in accordance with the requirements of the HT Act 2004, the Q&S Regulations and the HTA's Codes of Practice.
c) The establishment or the third party's procedure on obtaining donor consent includes how potential donors are identified and who is able to take consent.
d) Consent forms comply with the HTA Codes of Practice.
e) Completed consent forms are included in records and are made accessible to those using or releasing tissue and / or cells for a Scheduled Purpose.
C2 Information about the consent process is provided and in a variety of formats.
a) The procedure on obtaining consent details what information will be provided to donors. As a minimum, the information specified by Directions 001/2021 is included.
b) If third parties act as procurers of tissues and / or cells, the third party agreement details what information will be provided to donors. As a minimum, the information specified by Directions 002/2018 is included.
c) Information is available in suitable formats and there is access to independent interpreters when required.

d) There are procedures to ensure that information is provided to the donor or donor's family by trained personnel.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.
a) Staff involved in obtaining consent are provided with training on how to take informed consent in accordance with the requirements of the HT Act 2004 and Code of Practice on Consent.
b) Training records are kept demonstrating attendance at training on consent.

Governance and Quality

Standard
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.
a) There is an organisational chart clearly defining the lines of accountability and reporting relationships.
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.
d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.
e) There are procedures for tissue and / or cell procurement, which ensure the safety of living donors.
g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.
h) There are procedures for the management and quarantine of non-conforming consignments or those with incomplete test results, to ensure no risk of cross contamination.
i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded.

j) There are procedures detailing the critical materials and reagents used and where applicable, materials and reagents meet the standards laid down by the Medical Devices Regulation 2002 (SI 2002 618, as amended) (UK MDR 2002) and United Kingdom Conformity Assessed (UKCA).
l) There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and / or cells are transferred to another licensed establishment or establishments.
m) The criteria for allocating tissues and / or cells to patients and health care institutions are documented and made available to these parties on request.
o) There is a complaints system in place.
p) There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells.
q) There is a record of agreements established with third parties.
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 001/2021.
s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.
t) There are procedures for the re-provision of service in an emergency.
GQ2 There is a documented system of quality management and audit.
a) There is a quality management system which ensures continuous and systematic improvement.
b) There is an internal audit system for all licensable activities.
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.
a) There are clearly documented job descriptions for all staff.
b) There are orientation and induction programmes for new staff.

c) There are continuous professional development (CPD) plans for staff and attendance at training is recorded.
d) There is annual documented mandatory training (e.g. health and safety and fire).
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.
f) There is a documented training programme that ensures that staff have adequate knowledge of the scientific and ethical principles relevant to their work, and the regulatory context.
g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.
h) There is a system of staff appraisal.
i) Where appropriate, staff are registered with a professional or statutory body.
j) There are training and reference manuals available.
k) The establishment is sufficiently staffed to carry out its activities.
GQ4 There is a systematic and planned approach to the management of records.
a) There are procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records.
b) There is a system for the regular audit of records and their content to check for completeness, legibility and accuracy and to resolve any discrepancies found.
c) Written records are legible and indelible. Records kept in other formats such as computerised records are stored on a validated system.
d) There is a system for back-up / recovery in the event of loss of computerised records.
e) The establishment keeps a register of the types and quantities of tissues and / or cells that are procured, tested, preserved, processed, stored and distributed or otherwise disposed of, and on the origin and destination of tissues and cells intended for human application.
f) There are procedures to ensure that donor documentation, as specified by Directions 001/2021, is collected and maintained.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 001/2021.

h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.
i) The minimum data to ensure traceability from donor to recipient as required by Directions 001/2021 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.
j) Records are kept of products and material coming into contact with the tissues and / or cells.
k) There are documented agreements with end users to ensure they record and store the data required by Directions 001/2021.
l) The establishment records the acceptance or rejection of tissue and / or cells that it receives and in the case of rejection why this rejection occurred.
m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required.
GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.
a) Donors are selected either by the establishment or the third party acting on its behalf in accordance with the criteria required by Directions 001/2021.
b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 001/2021.
d) There is a system in place either at the establishment or at a third party acting on its behalf to record results of donor selection and associated tests.
e) Testing of donor samples is carried out using UKCA or CE marked diagnostic tests, in line with the requirements set out in Directions 001/2021.
f) Samples taken for donor testing are clearly labelled with the time and place the sample was taken and a unique donor identification code.
GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.
a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.
b) An audit trail is maintained, which includes details of when the tissues and / or cells were acquired and from where, the uses to which the tissues and / or cells were put, when the tissues and / or cells were transferred elsewhere and to whom.
c) The establishment has procedures to ensure that tissues and / or cells imported, procured, processed, stored, distributed and exported are traceable from donor to recipient and vice versa.

GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.
b) There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions.
c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.
d) There are procedures to identify and decide the fate of tissues and / or cells affected by an adverse event, reaction or deviation from the required quality and safety standards.
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.
a) There are documented risk assessments for all practices and processes.
b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.
c) Staff can access risk assessments and are made aware of local hazards at training.

Premises, Facilities and Equipment

Standard
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.
c) The premises have sufficient space for procedures to be carried out safely and efficiently.
e) There are procedures to ensure that the premises are secure and confidentiality is maintained.

f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.
c) There are procedures for cleaning and decontamination.
d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves.
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.
b) There are systems to deal with emergencies on a 24 hour basis.
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.
d) There is a documented, specified maximum storage period for tissues and / or cells.
PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.
b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport.
c) There is a system to ensure that traceability of tissues and / or cells is maintained during transport.
d) Records are kept of transportation and delivery.
e) Tissues and / or cells are packaged and transported in a manner and under conditions that minimise the risk of contamination and ensure their safety and quality.
f) There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained.
g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.

h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.
i) Primary packaging containing tissues and / or cells is labelled with the information required by Directions 001/2021.
j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions 001/2021.
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.
a) Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained.
b) Critical equipment is maintained and serviced in accordance with the manufacturer's instructions.
c) Equipment affecting critical processes and storage parameters is identified and monitored to detect malfunctions and defects and procedures are in place to take any corrective actions.
d) New and repaired equipment is validated before use and this is documented.
e) There are documented agreements with maintenance companies.
f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded.
g) Instruments and devices used for procurement are sterile, validated and regularly maintained.
h) Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate.
i) Staff are aware of how to report an equipment problem.
j) For each critical process, the materials, equipment and personnel are identified and documented.
k) There are contingency plans for equipment failure.

Disposal

Standard
D1 There is a clear and sensitive policy for disposing of tissues and / or cells.
a) The disposal policy complies with HTA's Codes of Practice.
b) The disposal procedure complies with Health and Safety recommendations.
c) There is a documented procedure on disposal which ensures that there is no cross contamination.
D2 The reasons for disposal and the methods used are carefully documented.
a) There is a procedure for tracking the disposal of tissue and / or cells that details the method and reason for disposal.
b) Disposal arrangements reflect (where applicable) the consent given for disposal.